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EXAMINER	
STAPLES, MARK	

ART UNIT	PAPER NUMBER
1637	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/776,711	SHAH, MRUGESH	
	Examiner	Art Unit	
	MARK STAPLES	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 March 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,9 and 11-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3, 9, and 11-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/5/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment of claims 1, 9, 11, 12, and 16 and the submission of new claims 16 and 17 in the paper filed on 03/02/2009 is acknowledged.

Claims 1, 3, 9, and 11-18 are pending and at issue.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Rejections that are Withdrawn

Claim Rejections Withdrawn In Part - 35 USC § 112 First Paragraph

2. The rejections of claims 1, 3, 9, and 11-16 in the part for reciting new matter of "synthetic petroleum" under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn. Applicant has amended the claims to recite "biosynthetic petroleum" in place of "synthetic petroleum". And while there is no literal support for the term "biosynthetic petroleum" in the originally filed application including the originally filed specification; the originally claimed methods recited combining a microorganism with recited material(s) to produce a product which would thus be biosynthetic, if accomplished. Thus the current amendments reciting "biosynthetic petroleum" are accepted.

Claim Rejections Withdrawn - 35 USC § 112 Second Paragraph

3. The rejections of claims 23 and 26 under 35 USC § 112 Second Paragraph are withdrawn in light of Applicant's removal of the word "plurality" from these claims and amendment to recite the number of primers supported by the specification.

Claim Rejections Withdrawn - 35 USC § 112 Second Paragraph

Omitting Essential Elements

4. The rejections of claims 1, 3, 9, and 11-15 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements is withdrawn. Applicant has amended the claims to recite a step of conversion. However, this step is not found to be enabled as given in the following section.

Rejections that are Maintained

Lack of Enablement

5. The rejection of claims 1, 3, 9, and 11-16 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is maintained. Applicant's arguments filed 03/02/2009 have been considered but they are not persuasive.

Cited References are Not Considered

Applicant's arguments with respect to cited references are not considered here as the cited references have not been submitted in a proper Information Disclosure Statement (see ***Improper Information Disclosure*** below).

Claim 1

Applicant argues that step a) of claim 1 is known in the art as "bioprospecting" and that Examiner appears to concur as this step does not appear to be specifically but generally challenged. As a matter of record, Examiner does not concur that step a) of claim 1 was known in the art either specifically or generally. The claim recites "said conversion" which is a conversion that is unknown in the art and where there is no known microorganisms capable of "said conversion" as recited. "Bioprospecting" for a heretofor unknown conversion and/or microorganism is not a matter of knowledge but a lack of guidance.

Applicant argues two points regarding step b) of claim 1. The gist of the first point is that Applicant need not provide the detailed processes of isolating the genes needed by subtractive hybridization as both gene isolation and subtractive hybridization were known in the art. However, Applicant is not applying either of these in a manner to enable the claimed invention. Subtractive hybridization merely points to genetic differences between organisms, as given in the last Office action. Applicant has not provided any guidance as to how to move from this to isolating the genes responsible for "said conversion". This is also the guidance that is not known in the art, much less well known, and this is essential guidance that instant application does not provide. The second point argued is that the cited teaching of Hamme et al., regarding how alkane biosynthetic systems evolved, is misinterpreted. Hamme et al. is not referring to the process of evolution of organisms but to how the different approaches to alkane metabolism will need to evolve/change so that alkane metabolism might eventually be

applied in chemical synthesis. In other words, Hamme et al. speak directly to the difficulty in just producing alkanes by microorganisms. Applicant claims to have a biosynthetic method for producing not just alkanes which are but a component of petroleum but for biosynthetic petroleum which is complex mixture of varied and multiple components.

Applicant argues that step c of claim 1 for transfecting genes is enabled. Applicant argues that transfection of a gene is known and thus the instant claims are enabled for transfecting. However, this is not the transfecting of the instant claims. Neither the instant applicant nor the art including the present state of the art enables the claims for transfecting genes (plural) the essential expressing of multiple genes acting in proper concert across multiple biosynthetic pathways to biosynthetically convert complex starting materials into a complex mixture which is biosynthetic petroleum.

Applicant argues that in step d the conditions of the biosynthetic conversion are known as conditions for synthetic conversion, i.e. without the use of microorganisms, are known. Applicant has not provided evidence the conditions for synthetic conversion are applicable to the conditions for biosynthetic conversion. In fact the art teaches otherwise as just the temperatures of biosynthetic conversion cannot be so high as to kill the microorganisms.

Claim 11

Applicant argues that recently the art teaches that natural microorganisms have been found which convert waste intro petrol/petroleum. First, Applicant does not reveal

what this "waste" is. Second, the claimed invention is not to microorganisms found in nature but to a host microorganism transfected by the genes responsible for the natural conversion.

Applicant argues the claims need not be enabled for commercial production since, with the exception of claim 16, there is no direct recitation of "commercial" in the claims. Applicant further argues that references cited by Examiner which mention or discuss commercial production among other things are not relevant to the instant claims and should be disregarded. Applicant then cites post filing date art which discusses commercial production and argues that these citations of Applicant are relevant and demonstrate that the instant claims are enabled. Thus Applicant's position appears to be conflicted. The crux is that petroleum is and for some time has been a commercial product. Thus it is to be excepted that the art which discusses petroleum or biosynthetic petroleum production will mention commercial production at least in passing. This does not by itself make this art irrelevant even to those instant claims which do not recite "commercial". While a goal may be commercial production, the art cited by Examiner expressly discusses other subject matter relevant to the instant claims as given in previous Office actions.

Applicant specifically argues that since claim 16 recites "best suited to commercial production" that the claim is not related to commercial production. However the claim specifically directs the reader to commercial production and thus commercial production is relevant as recited positively in the claim as a claim limitation.

New Objections and Rejections Necessitated by Amendment

Improper Information Disclosure

6. The information disclosure statement filed on 09/05/2008 dispersed throughout Applicant Arguments/Remarks Made in Amendment fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because the content requirements as discussed in MPEP § 609.04(a) are not complied with and because copies of non-patent literature have not been provided. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

New Claim Objections

7. Claim 18 is objected to because of the following informalities: for recitation of "synthetic petroleum" in line 2 when it appears that "biosynthetic petroleum" is intended. Appropriate correction is required.

New Claim Rejections - 35 USC § 112, First Paragraph

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 17 and 18 are rejected for reciting new matter of "obtaining a gene coding a protein capable of said conversion" under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The original specification and original claims describe genes (plural) capable of said conversion, and not a singular gene capable of said conversion. It is noted that the specification does refer to a probe to one of these genes and also refers to the gene of these genes which is responsible for the conversion, but the specification does not disclose the conversion as claimed as through one gene. Furthermore, neither the original specification nor the claims describe a gene encoding a protein much less a gene encoding a protein capable of the conversion. And it is noted that genes need not encode proteins, Duga et al. (2000) teach genes which do not encode proteins (see 2nd sentence of 5th paragraph on p. 233). And Pesole (2008) teaches that: "A large fraction of genes do not encode for proteins" (see particular point 1 on p. 2).

Claim Interpretation

10. As neither the claims nor the specification define the term "biosynthetic petroleum" this is reasonably interpreted to mean petroleum which is produced through biosynthesis, that is, through a process directly involving living organisms which can be microorganisms. American Heritage® Dictionary (retrieved 2009) and Encyclopaedia Britannica (retrieved 2009, "petroleum") are relied upon for definitions of petroleum. Synthetic petroleum is then reasonably interpreted to be a complex mixture containing

multiple components found in petroleum and/or multiple components chemically similar to those found in petroleum.

11. As neither the claims nor the specification define the term "biosynthetic coal" this is reasonably interpreted to mean coal which is produced through biosynthesis, that is, through a process directly involving living organisms which can be microorganisms. Encyclopaedia Britannica (retrieved 2009, “coal”) is relied upon for definitions of petroleum. Synthetic coal is then reasonably interpreted to be a complex mixture containing multiple components found in coal and/or multiple components chemically similar to those found in coal.

New Claim Rejections - 35 USC § 112, First Paragraph

Lack of Enablement

12. Claims 17 and 18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described by the court in *In re Wands*, 8 USPQ2d 1400 (CA FC 1988). *Wands* states at page 1404,

> "Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims."

The nature of the invention and breadth of claims

Claims 17 and 18 are broadly drawn to methods of producing products being or resembling the complex and the multiple components of petroleum or coal.

The unpredictability of the art and the state of the prior art

There is a great deal of unpredictability in field of biofuel production. Ethanol production has received a lot of attention owing to the availability of renewable feedstock from biomass. This technology is directed to production of just one compound, ethanol. Yet there is considerable difficulty in making ethanol production a viable process. The state of the art at the time of the claimed invention is revealed by Zaldivar et al. (2001, previously cited):

> "However, keeping a realistic perspective is important. The improvement achieved in the fermentation step with the help of metabolic engineering is just one of the aspects of an integrated process. Hence, several pieces still remain to be properly assembled (and optimized) before an efficient industrial configuration is acquired. It is therefore anticipated that once in operation, the current model technologies will need several cycles of improvement/ analysis, before optimization and competitiveness

are achieved" (see last paragraph on p. 30).

The post filing date art further confirms the unpredictability of this area. Jeffries et al. (2004, previously cited) convey: "However, the bioconversion of pentoses to ethanol still presents a considerable economic and technical challenge . . .." (see 3rd sentence on p. 496). Lin et al. (2006, previously cited) disclose: "In this field, although bioethanol production has been greatly improved by new technologies, there are still challenges that need further investigations. A further understanding of the ethanol fermentation needs to be reached" (see 2nd column, 1st paragraph, last 2 sentences on p. 627). And: "Recently, research has concentrated on the development of improved processes; however, there are still challenges that need further investigations" (see 2nd sentence under the section *Most promising prospects* on p. 635).

Quantity of Experimentation

The quantity of experimentation in this area is extremely large since there is significant number of parameters which would have to be studied to apply this technology, including variability of the fossil fuels such as coal from source to source, ability of the host microorganism to adapt and convert these varies sources to products found in petroleum or coal, ability of the host microorganism to produce the multitude of compounds claimed, and the conditions necessary for the microorganism to produce those compounds. The time table necessary to achieve efficacious investigation of these parameters would require a very large quantity of experimentation. This would require years of inventive effort, with each of the many intervening steps, upon effective reduction to practice, not providing any guarantee of success in the succeeding steps.

Working Examples

The specification has no working examples of the claimed invention.

Guidance in the Specification.

The specification provides no evidence that a transfected host microorganisms would be able to produce the products found in petroleum or coal. The specification does not provide support that a host microorganism would be able to produce such products and that a starting microorganism would have a gene capable of such conversion. As found in Table 1 of Ishizaki et al. (2001, previously cited), the recombinant *E. coli* producing P(3HB) is not superior to two starting microorganisms *P. extroquens* and *R. eutropha*. Furthermore, Choi et al. (1998, previously cited) show that several recombinant E. coli did not adequately generate product, as shown in Figure 3. Thus just making a transfected host microorganism does not guarantee it will adequately produce the products as claimed. The guidance provided by the specification amounts to an invitation for the skilled artisan to try and follow the disclosed instructions to use the claimed invention. The specification merely discloses that one follow the complex procedure of gene identification and transfection followed by even the more complex procedure of selecting and optimizing growth conditions of the host microorganism to produce a vast arrays of distinct products by one cultivation of the host microorganism. Furthermore, the specification provides inadequate guidance to identify the gene of the starting organism that would need to be transfected. The products claimed to be produced are chemically more complex than ethanol and the expectation of the state of the art is that a complex metabolic pathway with several enzymes (and hence several genes of the starting microorganism) would be needed to yield the complex mixture of complex products. Thorough review of the prior art fails to

show any enabled teachings of a transfected microorganism producing the multitude of products found in petroleum and coal.

Level of Skill in the Art

The level of skill in the art is deemed to be high.

Conclusion

In the instant case, as discussed above, the factor of unpredictability weighs heavily in favor of undue experimentation in this highly unpredictable art where the variables of transfection of genes into mircoorganisms to produce biosynthetic petroleum or biowynthetic coal depend upon numerous parameters such as what panel of genes may be needed, how the feedstack to be converted into fuel is to be pretreated, how the transfected microorganism is to be introduced into the feedstock and how its growth is to be maintained, and what the acceptable limits are of temperature, pressure, aeration or lack of aeration, and degree of mixing. Further, the prior art and the specification provides insufficient guidance to overcome the art recognized problems in the use of producing the complete range of products found in petroleum or coal by a gene from one specie of a starting microorganism. Thus given the broad claims in an art whose nature is identified as unpredictable, the large quantity of research required to define the unpredictable variables, the lack of guidance provided in the specification, the absence of a working example, and the negative teachings in the prior art balanced only against the high skill level in the art, it is the position of the examiner that it would require undue experimentation for one of skill in the art to perform the method of the claim as broadly written.

Conclusion

13. No claim is allowed.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Staples whose telephone number is (571) 272-9053. The examiner can normally be reached on Monday through Thursday, 9:00 a.m. to 6:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Mark Staples
/M. S./
Examiner, Art Unit 1637
May 25, 2009

/Kenneth R Horlick/
Primary Examiner, Art Unit 1637